APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,719	03/23/2004	Kenneth P. Hoyme	279.721US1	2654

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EXAMINER
KAHELIN, MICHAEL WILLIAM

ART UNIT	PAPER NUMBER
3762	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

	Application No.	Applicant(s)
Office Action Summary	10/806,719	HOYME ET AL.
	Examiner	Art Unit	
	Michael Kahelin	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE **3** MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *13 October 2006*.

2a) ☒ This action is **FINAL**.   2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1,3-24,26-32 and 51-56* is/are pending in the application.

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1,3,6,7,10-24,27-30,32 and 51-56* is/are rejected.

7) ☒ Claim(s) *4,5,8,9,26 and 31* is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a) ☐ All   b) ☐ Some * c) ☐ None of:

      1. ☐ Certified copies of the priority documents have been received.

      2. ☐ Certified copies of the priority documents have been received in Application No. _____.

      3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
    Paper No(s)/Mail Date *20061013*.

4) ☐ Interview Summary (PTO-413)
    Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1.   The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2.   Claims 1, 6, 7, 11, 18-22, 24, 25, 29, 30, 51, 53, and 55 rejected under 35 U.S.C. 102(b) as being anticipated by Shahandeh (US 6,532,389, hereinafter "Shahandeh").

3.   In regards to claims 1, 24, 51 and 53, Shahandeh discloses an IMD comprising memory (94) and a controller circuit (60) wherein the controller enters a memory scrubbing mode (316 and 320) with an increased rate of error checking when the controller determines the IMD is in a high-energy radiation environment (Fig. 7). Examiner is interpreting Shahandeh's "controller determine[ing] the implantable device is in a high-energy radiation environment" as being performed by the same method as claimed in claim 2 (i.e. detecting a rate of memory errors exceeding a threshold at Fig. 7's step of "Page Parity Error Detected?" The rate of errors is 1 per read cycle.). The "increased rate of error detection" is disclosed in the steps following element 314 in Figure 7 (i.e. by checking column and array parity bits). In other words, the controller determines that the device is in a high-energy radiation environment (col. 1, line 61; errors are caused by "high-energy radiation" environments) by detecting that a rate of

memory errors exceeds a programmable threshold error rate (i.e. at a rate of 1 per read cycle), wherein the memory scrubbing mode has an increased rate of error checking (i.e. at a higher rate of the number of columns per page).

4.   In regards to claims 6 and 29, the controller circuit exits the memory scrubbing mode when the IMD is no longer in the radiation environment (Fig. 7, "NO" at "Page Parity Error Detected?").

5.   In regards to claims 7 and 30, the determination is made by detecting a rate that is less than a threshold (zero per page).

6.   In regards to claim 11, the controller detects and corrects single bit errors (316 and 320).

7.   In regards to claim 18, the IMD includes an output and therapy circuit (40-58, 70 and 78).

8.   In regards to claims 19 and 20, the memory scrubbing mode is performed at a lower priority than the therapy (col. 14, line 22). The memory scrubbing is performed between therapies.

9.   In regards to claims 21 and 55, the IMD further comprises an electrical input and output to provide therapy to the heart (Figs. 1 and 2).

10.   In regards to claim 22, the IMD includes a cardioverter defibrillator (116).

Claim Rejections - 35 USC § 103

11.   The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12.   This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13.   Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shahandeh. Shahandeh discloses the essential features of the claimed invention, including detecting multiple bit errors (abstract), but does not disclose correcting multiple bit errors. However Shahandeh teaches that it is well known in the art (col. 2, line 28) to correct multiple bit errors to avoid corruption of large amounts of memory. Therefore, it would have been obvious to modify Shahandeh's invention by correcting multiple bit errors to avoid corruption of large amounts of memory.

14.   Claims 3, 10, 13, 14, 16, 17, 26-28, 32, 52, 54 and 56 rejected under 35 U.S.C. 103(a) as being unpatentable over Shahandeh in view of Foster et al. (US 2003/0036776, hereinafter "Foster"). Shahandeh discloses the essential features of the claimed invention except for utilizing a sensor to determine a high energy radiation environment exceeding background radiation, exiting the high-radiation mode after a

predetermined period of time, or enabling and disabling the high-radiation mode via an

RF transmitter associated with the source. Foster teaches of utilizing a sensor to

determine a high energy radiation environment exceeding background radiation (par.

0041) to protect the most sensitive components of the device, exiting the high-radiation

mode after a predetermined period of time (par. 0045) to only utilize the protective mode

during at-risk periods, or enabling and disabling the high-radiation mode via an RF

transmitter associated with the source (par. 0053) to accurately change modes only

during application of radiation. Therefore, it would have been obvious to one having

ordinary skill in the art at the time the invention was made to modify Shahandeh's

invention by utilizing a sensor to determine a high-energy radiation environment

exceeding background radiation to protect the most sensitive components of the device,

exiting the high-radiation mode after a predetermined period of time to only utilize the

protective mode during at-risk periods, or enabling and disabling the high-radiation

mode via an RF transmitter associated with the source to accurately change modes

only during application of radiation.

15.   Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over

Shahandeh in view of Foster et al. as applied to claim 13 above, and further in view of

Linberg (US 2002/0032470, hereinafter "Linberg"). The modified invention of

Shahandeh includes the essential features of the claimed invention except for

programmer connectivity to a global computer network. Linberg teaches of an

implantable cardiac rhythm management device whose programmer communicates with

a web-based data center to import expertise to the patient environment (abstract).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the modified invention of Shahandeh with a programmer with connectivity to a global computer network to allow a remote medical expert to diagnose problems, monitor the patient, or provide software enhancements to the implanted device.

16.   Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shahandeh in view of Ullestad et al. (US 6,635,048, hereinafter "Ullestad"). The modified invention of Shahandeh includes the essential features of the claimed invention except for providing drug therapy to the patient. Ullstad teaches of providing a drug delivery device with a back-up memory to provide a reliable device to treat a variety of diseases that require controlled release drugs. Therefore, it would have been obvious to provide the modified invention of Shahandeh with a drug delivery device to provide a reliable means to treat a variety of diseases that require controlled release drugs.

Allowable Subject Matter

17.   Claims 4, 5, 8, 9, 26, and 31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

18. Applicant's arguments filed 10/13/2006 have been fully considered but they are

not persuasive. Applicant argued that Shahandeh fails to disclose the newly-added

limitations of:

> "monitoring a number of errors encountered while accessing memory
>
> locations in a normal operation mode, using the monitored number of
>
> errors to determine a rate of memory errors per time period, comparing
>
> the rate of memory errors to a programmable threshold rate of memory
>
> errors per time period, and detecting that the rate of memory errors
>
> exceeds the programmable threshold error rate".

However, Shahandeh discloses the above limitations because the method of

Figure 7 is conducted in a "normal mode" because it is programmed to operate in

such manner. The disclosed method determines a rate of memory errors per

time period because the device determines an error during a read cycle, wherein

the read cycle is a "time period". Further, Shahandeh's device/method compares

the error rate to a threshold rate of one error per read cycle.

Conclusion

19. Applicant's amendment necessitated the new ground(s) of rejection presented in

this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37

CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE

MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later

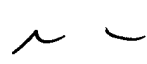than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Michael Kahelin whose telephone number is (571) 272-

8688. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number

for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the

Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR.

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For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MWK

1/31/07

Primary Examiner 3762

2/1/7